REMARKS

Formal Matters

Applicants have amended claims 54, 62, 65, 68, and 72. Support for these amendments may be found in the specification at, for example, paragraphs 19, 29, and 77. Applicants have cancelled claim 75 and added new claims 79-81. Support for these new claims may be found in the specification at, for example, paragraphs 13 and 29. Thus, no new matter has been added.

Claims 54-59, 61-74, and 76-81 are currently pending.

Enablement Rejection

In the Advisory Action mailed May 22, 2007, the Office maintained the rejection of claims 54-59 and 61-76 and newly rejected claims 77 and 78, under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for the reasons detailed in the Office Actions dated April 20, 2006, and October 6, 2006. (*See* Advisory Action at 2-3.) The Office argued that the claims are drawn to an unlimited number of microorganisms used in the fermentation step and therefore undue experimentation would be required to determine which exact species of microorganism works in the claimed invention. (*See* 4/20/06 Office Action at 3; 10/6/06 Office Action at 3-4.) Applicants respectfully traverse. However, without prejudice or disclaimer, Applicants have amended independent claim 54 by adding the phrase "wherein the microorganisms are bacteria or fungi."

Specifically, the Office asserts that "undue experimentation would be expected because Applicants have not even attempted to provide a single species of the claimed genus'." (4/20/06 Office Action at 4.) Contrary to the Office's assertion, Applicants did describe the collection and identification of the TW-S-7-1 isolate, belonging to the genus

Bacillus, which was used to produce collagen monomers according to the claimed methods. (*See* specification, examples 1-4, 6.) Applicants believe that the amended claims meet the enablement requirement, for reasons discussed in more detail below. However, Applicants have informed the undersigned that they will make an acceptable deposit of the TW-S-7-1 isolate if the Office requires such for allowance of the application. As set forth in 37 CFR § 1.809(c), in the event that an application for patent is otherwise in condition for allowance except for a required deposit and the Office has received written assurance that an acceptable deposit will be made, Applicant will be notified and given a period of time within which the deposit must be made. *See also* M.P.E.P. § 2411.03.

The Office also states that Applicants' response of May 7, 2007, does not "remedy or answer any questions regarding what or how [the method] produces the collagen monomers." (Advisory Action at 6.) Further, the Office asserts that "[c]learly it is some enzyme produced in the fermentation process, however, which enzyme is wholly unclear." (*Id.*) However, the Office is improperly requiring Applicants to explain the mechanism of their invention. It is well-established law that "it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989). As Applicants have previously stated, the examples clearly show that the disclosed methods produce the amount of collagen monomers required by the amended claims. (*See, e.g.*, 5/7/07 Nam Declaration at ¶ 7.)

Without such a description of the exact enzyme or mechanism of the invention, however, Applicants have fully enabled one of ordinary skill in the art to make and use

the invention. "For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient [for the enablement requirement] if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation." M.P.E.P. § 2164.02. Further, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Id.* § 2164.06 (citing *In re Wands*, 858 F.2d 731, 737, 8 USPQ.2d 1400, 1404 (Fed. Cir. 1988)).

The present specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Specifically, five examples are provided in the specification, which detail how the methods of the invention were used to isolate collagen monomers. (*See* specification, Examples 2-6, pages 18-25.) Examples 2, 3, and 4 describe the isolation of collagen monomers from avian, porcine, and shark tissues, respectively, using bacterial fermentation. Example 5 details the isolation of collagen monomers from avian tissues using yeast fermentation, while Example 6 details the isolation of type II collagen monomers from cartilage using bacterial fermentation.

Each of the five examples discloses experimental conditions in sufficient detail to enable one of skill in the art to practice the claimed invention. For instance, Example 2 details the amount and treatment of the avian collagen-containing starting material, culture conditions and preparation of the Gram (+) bacterium, and fermentation conditions, such as amount of loaded tissue, fermentation time, and rates of agitation

and aeration. Subsequent to fermentation, Example 2 also clearly explains the conditions used to purify the collagen monomers using an acidic solution and enzyme preparation, filtration, delipidation, centrifugation, and precipitation. Finally, as in the other examples, Example 2 clearly discloses how the resulting collagen product is analyzed using SDS-polyacrylamide gel electrophoresis (SDS-PAGE) for composition and purity.

Based on these teachings, one of skill in the art would be able to use the claimed collagen monomer isolation process without undue experimentation. Applicants have successfully performed the claimed methods, using the guidance provided by Example 3, with four different species of microorganisms. (*See* attached Declaration of Seah June Nam, Ph.D.) Applicants' success further demonstrates that undue experimentation would not be required to determine what species of microorganism will work with the claimed invention.

Furthermore, even if such routine experimentation is performed many times for various microorganisms before identifying those that work, "a *considerable* amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." M.P.E.P. §2164.06 (citing *In re Wands*, 858 F.2d 731, 737, 8 USPQ.2d 1400, 1404 (Fed. Cir. 1988) (emphasis added)). The M.P.E.P. provides an example of reasonable experimentation as presented in *United States v. Telectronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988), where the "court ruled that since one embodiment (stainless steel electrodes) and the method to determine dose/response was set forth in the specification, the specification was

enabling. The question of time and expense of such studies, approximately $50,000 and 6-12 months standing alone, failed to show undue experimentation." M.P.E.P. § 2164.06 I. Here, similar to the *Telectronics* case, the present specification discloses the working examples, which can be used to determine whether a bacterium or fungus can be used in the present invention. The Office "recognizes that the art is not complex." (10/6/06 Office Action at 5.) Therefore, this rejection is improper.

In light of the foregoing remarks, Applicants respectfully request that the enablement rejection of claims 54-59, 61-74, and 76-80 be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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